Clinical Study Results

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Study Sponsor: UCB Biopharma SRL

Treatment Studied: Certolizumab pegol

Protocol Number: C87077

Short Study Title: A study to learn if certolizumab pegol plus methotrexate works in participants who are already taking methotrexate

Thank you!

The study sponsor, UCB, thanks all the participants of this study. All the participants helped the researchers learn more about using certolizumab pegol in people with rheumatoid arthritis, also called RA.

This is a summary of the main results of this study. An independent, non-profit organization called CISCRP helped prepare this summary of the study results.

We think it is important to share the results with the participants and the public. We hope this summary helps the participants understand and feel proud of their important role in medical research.

The purpose of this summary is only to share information. If you need medical advice, please contact your doctor. If you participated in this study and have questions about the results, please speak with your study doctor or the study staff.

Why was the research needed?

Before a treatment is available to all patients, researchers do clinical studies to get information about how well the treatment works and about how safe it is.

The researchers in this study wanted to learn if certolizumab pegol plus methotrexate worked in a large number of participants with active RA. They also wanted to learn if the participants had any medical problems during the study.

RA is an immune system disease that causes pain, swelling, and damage to joints. Doctors often suggest that patients first take methotrexate to treat their RA. But, sometimes people with RA need other treatments to control their RA.

Certolizumab pegol blocks a protein that is 1 of the causes of RA. In this study, the researchers wanted to learn how continued treatment with certolizumab pegol plus methotrexate worked. They studied this in participants whose RA improved after initial treatment.

What were the main questions studied?

The main questions the researchers wanted to answer in this study were:

- How many of the participants had their RA improve?
- What medical problems did the participants have during the study?

Who participated in the study?

Men and women with RA participated in this study. They were 20 to 86 years old.

In this study, the researchers planned to include participants who:

- Had RA for at least 6 months but not for more than 15 years
- Had RA that the researchers considered active based on their number of tender and swollen joints and blood tests results showing inflammation
- Took a steady dose of 10 to 25 milligrams of methotrexate for at least 3 months in a row before the study

The study included 333 participants who received study treatments. The study took place in 3 countries: Canada, France, and the US.

Each participant was in the study for up to 48 weeks, but the whole study lasted about 3 years. The study started in January 2008 and ended in March 2011.

What treatments did the participants take?

There were 2 main parts to this study. Part 1 lasted for 18 weeks. During Part 1, the participants received certolizumab pegol, methotrexate, and a placebo.

Methotrexate was taken as a pill. Certolizumab pegol and the placebo were given through a needle under the skin, also called an injection. The doses of methotrexate and certolizumab pegol were measured in milligrams, also called mg. The placebo injection did not have any certolizumab pegol or medicine in it. The placebo was used to make sure the participants received the same number of injections each time they received them.

During Part 1, the participants, study doctors, and study staff all knew what study treatments the participants were receiving. UCB staff also knew.

During Part 1:

- 333 participants received certolizumab pegol plus methotrexate.
- The participants who stayed in Part 1 for at least 6 weeks also received the placebo.

Part 2 started at Week 18 and lasted for 16 weeks. During Part 2 the participants received either:

- Certolizumab pegol plus methotrexate
- The placebo plus methotrexate

During Part 2, none of the participants or study doctors knew what study treatment each participant was taking. This part was done this way because knowing what treatment the participants are taking can affect the results of the study. After the study was completed, UCB learned what treatment each participant received so they could create a report of the results.

The researchers used a computer program to randomly choose if the participants received certolizumab pegol plus methotrexate or placebo plus methotrexate in Part 2. This helped make sure the treatments were chosen fairly and comparing the results of the treatments was as accurate as possible.

In Part 2, there were 3 treatment groups:

- Group 1: 69 participants received the placebo plus methotrexate.
- Group 2: 70 participants received 200 mg of certolizumab pegol plus methotrexate. They also took the placebo.
- Group 3: 69 participants received 400 mg of certolizumab pegol plus methotrexate. They also took the placebo.

The charts below show the treatments the researchers planned to study.

Part 1

18 weeks

The participants took a steady dose of 10 to 25 mg of methotrexate every week for 18 weeks.

First day of the study
- 2 injections for a total of 400 mg certolizumab pegol

At Weeks 2 and 4
- 2 injections for a total of 400 mg certolizumab pegol

Weeks 6 through 16

Every 2 weeks:
- 1 injection of 200 mg certolizumab pegol
- 1 injection of the placebo

Part 2

16 weeks

All participants took a steady dose of 10 to 25 mg of methotrexate every week for 16 weeks.

14 weeks

Group 1

Every 2 weeks:
- 2 injections of the placebo

Group 2

Every 2 weeks:
- 1 injection of 200 mg certolizumab pegol and 1 injection of the placebo

Group 3

For 12 weeks:
- 2 injections for a total of 400 mg certolizumab pegol every 4 weeks
- 2 injections of the placebo every 2 weeks between the certolizumab pegol injections

After the final injection of certolizumab pegol:
- 2 injections of the placebo

What happened during the study?

This section shows how the study was planned to be done.

Before the study started, all the participants first learned about the study and then decided to join. This is called "informed consent." The study doctors and study staff then asked about their medical history and checked their health to make sure they could join the study. This part lasted up to 4 weeks.

During the study:


The study doctors counted the participants' number of swollen and painful joints, and rated how their RA was doing.


The participants visited the clinic every 2 weeks.


The study doctors kept track of any medical problems reported by the participants or observed by the doctors or study staff.


The participants rated how their RA was making them feel.


The participants gave blood and urine samples at some clinic visits.

The study had 2 main parts.

Part 1 lasted 18 weeks. During Part 1, all the participants received the same study treatments.

At Week 16, the researchers checked to see if the participants' RA improved. To do this, the researchers used the "ACR20 criteria," also called the ACR20. The ACR20 is a way to look at RA improvement and is based on:

- The number of swollen and tender joints
- The study doctor's rating of how the participants' RA was doing
- The participants' rating of how their RA was making them feel
- The results of a blood test called CRP that measured inflammation

The participants with at least 20% improvement in their RA met the ACR20 criteria and were called "ACR20 responders." Only the ACR20 responders could join Part 2 of the study.

The participants who were not ACR20 responders had a final clinic visit 12 weeks after their final injection and then left the study.

Part 2 lasted 16 weeks. During Part 2, the participants received study treatments based on the group they were in.

UCB originally planned that the participants would be in Part 2 of the study for up to 20 weeks. During the study, UCB shortened this time to 16 weeks. This was done to lessen the amount of time that the participants received the placebo.

After Part 2, the participants could choose to join another certolizumab pegol study. The participants who did not join the other study had a final clinic visit 12 weeks after their final injection.

What were the results of the study?

This is a summary of the main results from this study. These are the results from all the participants combined. The individual results of each participant might be different and are not in this summary.

Deciding which treatments work best usually takes results from several studies. Other studies may provide new information or different results. Always talk to a doctor before making any treatment decisions.

The results in this section include 209 participants who were ACR20 responders at Week 16 and joined Part 2 of the study. The results do not include the 124 participants who left the study before joining Part 2.

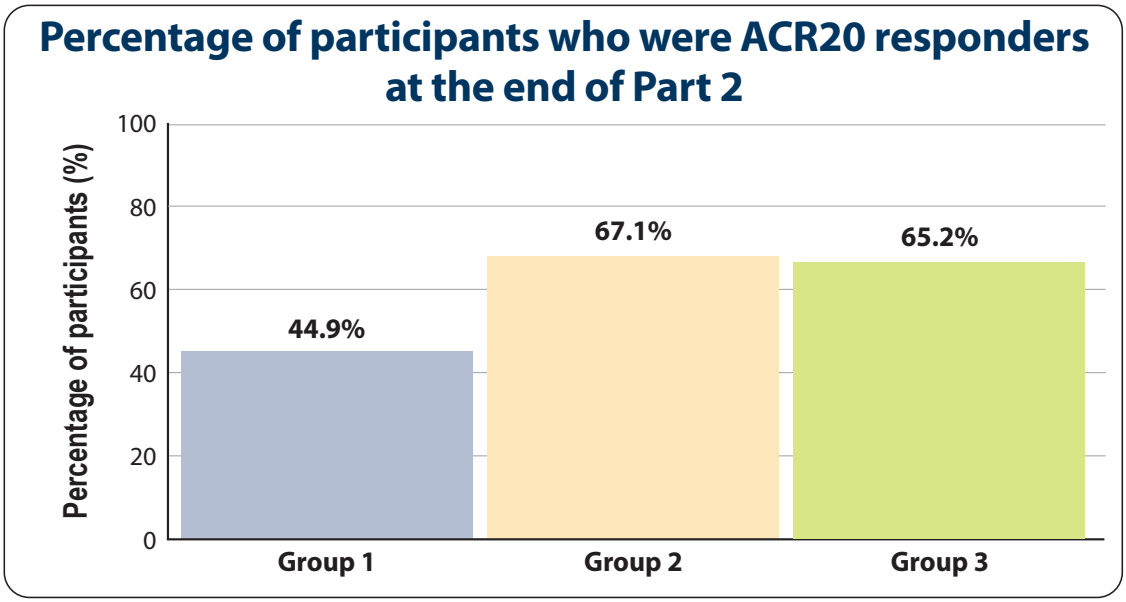
How many of the participants had their RA improve?

A higher percentage of participants had their RA improve in the groups that received certolizumab pegol plus methotrexate than in the group who received placebo plus methotrexate. The researchers considered participants who were ACR20 responders at the end of Part 2 as “improved.”

The percentage of ACR20 responders at the end of Part 2 in each group is shown below. During Part 2, the participants in Group 1 received the placebo plus methotrexate and the participants in Groups 2 and 3 received certolizumab pegol plus methotrexate.

- 44.9% of participants in Group 1. This was 31 out of 69 participants.
- 67.1% of participants in Group 2. This was 47 out of 70 participants.
- 65.2% of participants in Group 3. This was 45 out of 69 participants.

The graph below shows these results:



What medical problems did the participants have?

This section is a summary of the medical problems the participants had during the study that the doctors thought might be related to the treatments. These medical problems are called “adverse reactions.” Some participants had more than 1 adverse reaction. If the doctors thought a participant’s RA got worse due to the study treatment, this was considered an adverse reaction.

An adverse reaction is considered “serious” when it puts the participant’s life at risk, requires hospitalization, causes disability, causes a baby being born with medical problems, or may have turned into one of these problems if not treated.

The adverse reactions shown in this summary may or may not be caused by the treatments in the study. The results from several studies are needed to decide if a treatment causes an adverse reaction.

The results for Part 1 and Part 2 are shown separately. This is because in Part 1 all participants received the same study treatments, but in Part 2 they received 1 of 3 different study treatments. The results include adverse reactions that happened up to 84 days after participants’ final study treatment injection for the final part they were in.

How many of the participants had serious adverse reactions?

In Part 1, serious adverse reactions happened in:

- 1.8% of the participants. This was 6 out of 333 participants.

None of the participants died due to serious adverse reactions during Part 1. This was 0 out of 333 participants.

In Part 2, serious adverse reactions happened in:

- None of the participants in Group 1. This was 0 out of the 69 participants.
- 4.3% of the participants in Group 2. This was 3 out of 70 participants.
- 1.4% of the participants in Group 3. This was 1 out of 69 participants.

None of the participants died due to serious adverse reactions during Part 2.

What serious adverse reactions did the participants have?

The serious adverse reactions in Part 1 are shown in the table below. Some participants had more than 1 serious adverse reaction.

Serious adverse reactions in Part 1

	Certolizumab pegol plus methotrexate (out of 333 participants)
Infection in the deeper layer of the skin	0.6% (2)
Inflammation of the kidneys, usually due to bacteria	0.3% (1)
Inflammation of the large intestine, also called the colon	0.3% (1)
Lung infection	0.3% (1)
Lung infection caused by the bacteria called Streptococcus pneumoniae	0.3% (1)
Sudden loss of kidney function	0.3% (1)

The serious adverse reactions in Part 2 are shown in the table below. Some participants had more than 1 serious adverse reaction.

Serious adverse reactions in Part 2

	Placebo plus methotrexate	Certolizumab pegol plus methotrexate	
	Group 1 (out of 69 participants)	Group 2 (out of 70 participants)	Group 3 (out of 69 participants)
Fever	0.0% (0)	1.4% (1)	0.0% (0)
Illness that causes some of the same types of problems as a disease called lupus, but is not lupus	0.0% (0)	1.4% (1)	0.0% (0)
Infection of the mouth caused by yeast	0.0% (0)	1.4% (1)	0.0% (0)
Inflammation of the throat caused by a virus called herpes	0.0% (0)	1.4% (1)	0.0% (0)
Kidney infection	0.0% (0)	1.4% (1)	0.0% (0)
Lung infection	0.0% (0)	1.4% (1)	0.0% (0)
Bubble called a cyst under the skin	0.0% (0)	0.0% (0)	1.4% (1)
Too much fluid in the sac that surrounds the heart	0.0% (0)	1.4% (1)	0.0% (0)

How many of the participants had any adverse reactions?

In Part 1, 28.8% of the participants had adverse reactions that were serious or not serious. This was 96 out of 333 participants.

In Part 2, adverse reactions that were either serious or not serious happened in:

- 15.9% of the participants in Group 1. This was 11 out of 69 participants.
- 28.6% of the participants in Group 2. This was 20 out of 70 participants.
- 11.6% of the participants in Group 3. This was 8 out of 69 participants.

What adverse reactions did the participants have?

This section includes adverse reactions that happened in 5% or more of all the participants in Part 1 and 5% or more of the participants in any treatment group in Part 2. This means these adverse reactions happened in at least 1 out of every 20 participants in each group. There were other adverse reactions in each part, but these happened in fewer participants in each group.

In Part 1, the adverse reaction that happened in 5% or more of the participants was:

- Infection of the nose, sinuses, and throat in 5.1% of the participants. This was 17 out of 333 participants.

In Part 2, the adverse reactions that happened in 5% or more of the participants in any treatment group were:

- RA in 5.8% of the participants in Group 1
- Infection of the body parts that make and carry urine in 5.7% of the participants in Group 2

These results are shown in the table below.

Adverse reactions in 5% or more of participants in any treatment group in Part 2

	Placebo plus methotrexate	Certolizumab pegol plus methotrexate	
	Group 1 (out of 69 participants)	Group 2 (out of 70 participants)	Group 3 (out of 69 participants)
RA	5.8% (4)	1.4% (1)	0.0% (0)
Infection of the body parts that make and carry urine	0.0% (0)	5.7% (4)	2.9% (2)

How has this study helped patients and researchers?

The results of this study have helped researchers learn more about using certolizumab pegol in people who have RA. The results may be used in other studies to compare certolizumab pegol with other treatments for people who have a similar condition.

Deciding which treatments work best for patients almost always takes results from several studies. This summary shows only the main results from this one study. Other studies may provide new information or different results.

The purpose of this summary is only to share information. If you need medical advice about your own health or situation, please contact your doctor.

When this study ended, further clinical studies with certolizumab pegol were planned.

Where can I learn more about this study?

You can find more information about this study at the website listed below:

- https://clinicaltrials.gov/ct2/show/NCT00580840?term=C87077&rank=2
- https://www.clinicaltrialsregister.eu/ctr-search/search?query=2007-005288-86

If you have questions about this study, you can contact UCB by email at datasharing@ucb.com.

Study Information

Protocol Number: C87077

Study Sponsor: UCB Biopharma SRL sponsored this study. It was previously called UCB Pharma SA is and is referred to as UCB in this summary.

Full Study Title: A Phase IIIb, open-label, run-in and double-blind, placebo-controlled, randomized study to evaluate the safety and efficacy of certolizumab pegol administered concomitantly with stable-dose methotrexate in patients with active rheumatoid arthritis

National Clinical Study Number: NCT00580840

EudraCT number: 2007-005288-86

Thank you!

Participants in clinical studies belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

Glossary

Description	Also called
Bubble called a cyst under the skin	A bubble made of abnormal cells, which may contain air, fluid, or soft material. Also called “dermal cyst”.
Fever	Pyrexia
Illness that causes some of the same types of problems as a disease called lupus, but is not lupus	Lupus-like syndrome
Infection in the deeper layer of the skin	Cellulitis
Infection of the body parts that make and carry urine	Urinary tract infection
Infection of the mouth caused by yeast	Oral candidiasis
Infection of the nose, sinuses, and throat	Upper respiratory tract infection
Inflammation of the kidneys, usually due to bacteria	Pyelonephritis
Inflammation of the large intestine, also called the colon	Colitis
Inflammation of the throat caused by a virus called herpes	Herpes pharyngitis
Lung infection	Pneumonia
Lung infection caused by the bacteria called Streptococcus pneumoniae	Pneumococcal pneumonia
Sudden loss of kidney function	Renal failure acute
Too much fluid in the sac that surrounds the heart	Pericardial effusion

This summary was last updated on 03 January 2020.
Final clinical study report date is 25 September 2011.